

**PharmaSmart***Be Smart. Track Your Blood Pressure.***510(k) Summary**

(per 21 CFR 807.92)

MAY - 1 2007

I. Applicant:

PharmaSmart Inc.
3495 Winston Place, Bldg A, Ste. 1,
Rochester, N.Y.
14623, U.S.A

Contact Person: Lisa Goodwin, Chief Technology Officer
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II. Device Name

Proprietary Name: PharmaSmart PS1000/PS1500/PS2000 Public Use
Blood Pressure Monitor
Common/ Usual Name: Non-Invasive Blood Pressure Monitor
Classification Name: Noninvasive blood pressure measurement system.
Regulation Number: 870.1130
Product Code: DXN
Classification: 2

III. Predicate Devices

The PharmaSmart PS1000/PS1500/PS2000 Public Use Blood Pressure Monitor are substantially equivalent to the LC500 from Lifeclinic International and the 9303 Neonatal/Adult Vital Signs Monitor from CAS Medical Systems. The LC500 was cleared by the FDA on August 31, 2004 under 510(k) K040562. The 9303 was cleared by the FDA on November 2, 1998 under 510(k) K982776.

IV. Intended Use of the Device

The PharmaSmart Models PS-1000, PS-1500 and PS-2000 are indicated for use for non-invasive oscillometric blood pressure and pulse rate monitoring by the general public in a sit down kiosk form. The device does not perform any diagnoses; it only provides pressure and rate data to the users, who are advised to consult a physician.

V. Description of the Device

The PharmaSmart Blood Pressure kiosks Models PS-1000, PS-1500 and PS-2000 provide a self service means for measuring and tracking an individual's blood pressure (both diastolic and systolic) and pulse rate. The unattended kiosk can be installed in retail locations and is typically associated with pharmacy operations. Blood pressure readings are taken automatically by the



customer with no operator assistance required. Readings are reported on the LCD display, printed on an optional thermal printer, or stored on an optional smart card for long term tracking.

The PharmaSmart Blood Pressure kiosk provides a self-contained system for measuring and reporting blood pressure and pulse. The user interface consists of a simple membrane keypad with 3 buttons (4 buttons for some language translations) for user control, an LCD monitor for feedback, an automatically inflating blood pressure cuff to take readings and an optional thermal printer for hard copy output.

The core functionality of the system is to take and record blood pressure readings. This is accomplished by the user with no assistance required. When seated at the kiosk the user's arm is comfortably inserted into the automatically inflating blood pressure cuff. When the reading is initiated using the membrane keyboard the cuff automatically inflates and deflates and records the systolic and diastolic blood pressure readings along with the user's pulse.

VI. Technical Characteristics

The NIBP module within the PharmaSmart Blood Pressure kiosk derives a patient's systolic, diastolic, and mean arterial blood pressures by acquiring pressure pulses through a series of controlled deflation steps of an inflated cuff (oscillometric method).

The PharmaSmart Blood Pressure kiosk has the same intended use and similar technological characteristics as the predicate device and thus is substantially equivalent.

VII. Testing

The PharmaSmart Blood Pressure kiosk has undergone clinical evaluation and bench testing and meets the requirements of AAMI SP10:2002. In addition, the device meets the following standards:

- IEC 60601-1 Medical electrical equipment - General requirements for safety
- IEC 60601-2-30 Particular Requirements for the Safety of BP Monitor
- IEC 60601-1-2 and EN5501 1 Electromagnetic Compatibility



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Pharma-Smart LLC
c/o Ian Gordon
Senior Vice President
Emergo Group, Inc.
2519 McMullen Booth Road, Suite 510-295
Clearwater, FL 33761

Re: K063137

Trade Name: PharmaSmart Public Use Blood Pressure Monitor, Models PS-1
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: April 13, 2007
Received: April 16, 2007

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

The PharmaSmart Models PS-1000, PS-1500 and PS-2000 are indicated for use for non-invasive oscillometric blood pressure and pulse rate monitoring by the general public in a sit down kiosk form. The device does not perform any diagnoses; it only provides pressure and rate data to the users, who are advised to consult a physician.

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off) K063137
Division of Cardiovascular Devices
510(k) Number Thimmimar